II. REMARKS

Claims 1 to 8 are pending of which claims 1, 5 and 6 are independent. Claims 1, 4, 5, and 6 are amended. Support for the claim amendments may be found in the specification and claims as originally filed. *See, for example*, page 9, lines 1 to 3. Therefore, no new matter is added by way of these amendments.

The Applicants acknowledge the finality of the restriction requirement but maintain their traversal. The Applicants submit that election of a single nucleotide sequence is improper and the Applicants believe no serious burden would result by the search and examination of at least ten nucleotide sequences. The election of a single nucleic acid sequence contravenes the USPTO policy as set forth in the Manual of Patent Examining Procedure (M.P.E.P.) stating that "to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Commissioner has decided ... to permit a reasonable number of such nucleotide sequences to be claimed in a single application." (M.P.E.P., 8th ed., rev. 4, October 2005, Section 803.04). The M.P.E.P. further provides that "[i]t has been determined that normally ten sequences constitute a reasonable number for examination purposes." (emphasis added) *Id.* While the Examiner requires that a single nucleotide sequence be selected, she provided no reason for this deviation from articulated USPTO policy.

1. Objections to the Specification:

The Examiner objected to the disclosure because it allegedly contains embedded hyperlinks. Office Action at page 2. The Applicants respectfully traverse this objection to the specification.

The M.P.E.P. clearly states that:

> Where the hyperlinks and/or other forms of browser-executable codes themselves rather than the contents of the site to which the hyperlinks are directed are part of applicant's invention and it is necessary to have them included in the patent application in order to comply with the requirements of 35 U.S.C. 112, first paragraph, and applicant does not intend to have these hyperlinks be active links, examiners should not object to these hyperlinks.
>
> M.P.E.P. § 608.01(VII), emphasis added.

Because there are no active embedded hyperlinks in the specification, the Applicants respectfully request withdrawal of the objection to the specification.

2. Claim Rejection under 35 U.S.C. § 101:

Claims 1 to 8 were rejected under 35 U.S.C. § 101, because the claimed invention is allegedly "not supported by either a specific or substantial asserted utility or a well established utility." Office Action at page 2. The Applicants respectfully traverse this rejection.

The Examiner admits that the specification discloses many uses for the claimed invention "including use as molecular tags to isolate genetic regions, isolate genes, map genes and determine gene function (page 13), to determine if genes are members of a particular gene family, to obtain full length genes (page 14), to isolate promoters and flanking sequences (page 32), for use in marker assisted breeding programs, to hybridize to its complement, to encode proteins, to obtain molecules from other plants (page 30), and to determine whether a plant contains a mutation (page 32)." *Id.* at page 3. However, the Examiner appears to consider none of these utilities specific to the polynucleotides claimed.

One use of the elected SEQ ID NO: 11 can be shown by a BLASTN analysis. A BLASTN analysis is a well-known and conventional technique that can be used to obtain

information on nucleic acid sequences. *See* specification page 5, lines 19 to 28. One result from a BLASTN analysis of the claimed SEQ ID NO: 11 is shown next. As these results show, the claimed nucleotide sequence shows 99 percent identity to a storage-protein sequence obtained from *Triticum aestivum*.

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> gi|23071519|dbj|BJ216434.1|  BJ216434 Y. Ogihara unpublished cDNA
library, Wh Triticum aestivum cDNA clone wh12e03 3', mRNA sequence.
Length=539
Score =  507 bits (256),  Expect = 6e-141
 Identities = 259/260 (99%), Gaps = 0/260 (0%)
 Strand=Plus/Minus
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This sequence was obtained by Kawaura, K., Mochida, K., and Ogihara, Y. and disclosed in a scientific paper entitled "Expression Profile of Two Storage-Protein Gene Families in Hexaploid Wheat Revealed by Large-Scale Analysis of Expressed Sequence Tags" published in *Plant Physiol.* **139 (4)**, 1870–1880, 2005. All information above is readily available from conducting the BLASTN analysis of SEQ ID NO: 11 through the National Center of Biotechnology Information (NCBI) website.

The specification discloses, for example, that the nucleic acid molecule encodes a wheat protein, or fragment thereof, exhibiting a BLAST score of greater than 120, preferably between about 1450 and about 120, and even more preferably greater than 1450 with its homolog. *See* specification at page 18, lines 20 to 23. High homology to a wheat protein is one of the preferred embodiments of the invention. *Id.* at page 18, lines 8 to 19. In other words, SEQ ID NO: 11 (as one example) has utilities specific to it and not generally applicable to any nucleic acid. For instance, SEQ ID NO: 11 can be used to isolate genes, map genes, and determine gene function associated with protein storage. These utilities are credible, substantial, and well-established;

they are neither vague nor impractical. The Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so in the present case.

The utilities disclosed in the specification must be accepted as factually sound unless the Patent Office cites information that undermines the credibility of the assertion. *In re Brana*, 51 F.3d 1560, 1567, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995). As the Examiner is aware, "a 'rigorous correlation' need not be shown in order to establish practical utility; 'reasonable correlation' is sufficient." *See, Fujikawa v. Wattanasin*, 93 F.3d 1559, 1565, 39 U.S.P.Q.2d 1895, 1900 (Fed. Cir. 1996), emphasis added. "An Applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of the compound or composition, arguments or reasoning, documentary evidence, or any combination thereof." M.P.E.P. § 2107.03, at page 2100-43. The BLASTN analysis provides such a reasonable correlation through sequence identity: a 99 percent identity to a storage-protein sequence obtained from *Triticum aestivum* is a reasonable correlation.

In conclusion, because the Applicants need only establish a single utility to satisfy 35 U.S.C. § 101, and have done so with sufficient specificity and reasonable correlation in the present application, the rejection under 35 U.S.C. § 101 is incorrect and the Applicants respectfully request its withdrawal.

3. Claim Rejections under 35 U.S.C. § 112, first paragraph:

Claims 1 to 8 were rejected under 35 U.S.C. § 112, first paragraph, because the claimed invention is allegedly "not supported by either a specific or substantial asserted utility or a well established utility." Office Action at page 6. The Applicants respectfully traverse this rejection

and contend that this rejection has been overcome by the arguments set forth above with respect to the rejection under 35 U.S.C. § 101.

Claims 1 to 4, 6, and 8 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. *Id.* at page 7. The Applicants respectfully traverse.

The Examiner admits that SEQ ID NO: 11 meets the written description requirement of 35 U.S.C. § 112, first paragraph. *Id.* The Examiner goes on to state "(h)owever, SEQ ID NO: 11 is an EST, and is less than a full length open reading frame. It appears to be a fragment of a larger protein since it was isolated from a Triticum aestivum cDNA library." *Id.* Not only has the Examiner not provided any evidence to support this contention but even if true, her position is contrary to the law.

The purpose of the written description requirement is to ensure that the inventor had possession of the claimed subject matter, *i.e.*, to ensure that the inventors actually invented what is claimed. *Gentry Gallery Inc. v. Berkline Corp.*, 134 F.3d 1473, 1479, 45 U.S.P.Q.2d 1498, 1503 (Fed. Cir. 1998); *Lockwood v. American Airlines*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); *In re Alton*, 76 F.3d 1168, 1172, 37 U.S.P.Q.2d 1578, 1581 (Fed. Cir. 1996). In accordance with this purpose, the Applicants need not "describe," in the sense of Section 112, all things that are encompassed by the claims. To contend otherwise would contradict established jurisprudence, which teaches that a patent may be infringed by technology developed after a patent issues. *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251, 9 U.S.P.Q.2d 1461, 1464 (Fed. Cir. 1989). A related, and equally well-established principle of patent law is that claims "may be broader than the specific embodiment disclosed in

a specification." *Ralston-Purina Co. v. Far-mor-Co*, 772 F.2d 1570, 1575, 227 U.S.P.Q. 177, 179 (Fed. Cir. 1985) (*quoting In re Rasmussen*, 650 F.2d 1212, 1215, 211 U.S.P.Q. 323, 326 (C.C.P.A. 1981)). Thus, in order for the Applicants to describe each and every molecule encompassed by the claims, it is not required that every aspect of those nucleic acid molecules be disclosed. *In re Alton*, 76 F.3d at 1175, 37 U.S.P.Q.2d at 1584 (if a person of ordinary skill in the art would, after reading the specification, understand that the inventors had possession of the claimed invention, even if not every nuance, then the written description has been met).

It is well-settled law that each nucleic acid molecule within a claimed genus does not need to be described by its complete structure. An adequate written description of a genus of nucleic acids may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997) (emphasis added). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.* In contrast to the mere name "cDNA" provided in *Eli Lilly*, the Applicants have provided a detailed chemical structure by way of the nucleic acid sequence of SEQ ID NO: 11, as well as complements and specified variations thereof. This chemical structure clearly distinguishes molecules in the claimed genus from molecules not in the claimed genus. The Applicants have therefore satisfied the *Eli Lilly* test for written description.

The fundamental factual inquiry for satisfying the written description requirement is whether the specification conveys with reasonable clarity to those skilled in the art, as of the

filing date sought, that the Applicants were in possession of the invention as now claimed. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q. 2d 1111, 1117 (Fed. Cir. 1991). An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 U.S.P.Q.2d 1961, 1966 (Fed. Cir. 1997); M.P.E.P. § 2163.02. In light of the disclosure made by the Applicants in the specification one of ordinary skill in the art at the time the application was filed would have readily recognized that the Applicants were in possession of the invention as claimed. The Examiner has offered no evidence to demonstrate why one of ordinary skill in the art would reasonably doubt that the invention has not been adequately described in the present disclosure.

Moreover, the specification provides an adequate description of the claimed invention because it demonstrates to one skilled in the art that the Applicants were in possession of the claimed genera of nucleic acid molecules when the application was filed. The Applicants have provided a detailed chemical structure, *i.e.*, the nucleic acid sequence, of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, and 18. Nucleic acid molecules falling within the scope of claims 1 to 4, 6, and 8 are readily identifiable and one of ordinary skill in the art can readily identify whether a particular sequence meets the claimed characteristics or not. The fact that the nucleic acid molecules may comprise additional sequences or variations is beside the point. Such modifications are readily envisioned by one of ordinary skill in the art and disclosed throughout the specification.

In conclusion, the Applicants respectfully submit that the rejections under 35 U.S.C. § 112, first paragraph, are improper and the Applicants respectfully request reconsideration and withdrawal of these rejections.

4. Claim Rejections under 35 U.S.C. § 102:

Claims 1 to 8 were rejected under 35 U.S.C. § 102(b) as allegedly "being anticipated by products O3003 and O4378 of the 1991 Sigma Chemical Catalog." Office Action at page 12. As a preliminary matter, the Applicants respectfully remind the Examiner that claims 1 to 8 claim sequences other than the elected SEQ ID NO: 11. However, as the Examiner's rejections are focused on SEQ ID NO:11, the Applicants traverse accordingly.

"It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1369, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986). Further, "an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device." *In re Donohue*, 766 F.2d 531, 534, 226 U.S.P.Q. 619, 621 (Fed. Cir. 1985). The Examiner has applied an untenable interpretation of the claims to cover small fragments, *i.e.*, molecules as short as four nucleotides, and thus concludes that the claims are anticipated. However, whatever else the 1991 Sigma Chemical Catalog teaches, it does not disclose any one of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, 18 or the complements thereof. Absent a teaching of each and every element of the claims, including the nucleotide sequences of SEQ ID NOs: 7, 9, 11, 12, 13, 14, 15, 16, 17, 18 or the complements thereof, the 1991 Sigma Chemical Catalog cannot anticipate claims 1 to 8.

The Applicants remind the Examiner that during examination, the "claims must be given their broadest reasonable interpretation", M.P.E.P. § 2111 (emphasis added), and this interpretation must be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999). One of ordinary skill in the art would not reasonably interpret a short sequence of four dAs or dTs , as identical to, for example, SEQ ID NO: 11 or its complement, both of which are 392 bases in length. Therefore, the Applicants respectfully submit that neither product O3003 nor product O4378 of the 1991 Sigma Chemical Catalog anticipates any of the sequences claimed in claims 1 to 8. The Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1 to 8 were also rejected under 35 U.S.C. § 102(b) as allegedly "being anticipated by Fodor (US Patent 6,582,908)." *Id.* at page 13. The Applicants respectfully traverse this rejection.

Once again, the Examiner has applied an untenable interpretation of the claims to cover small fragments. One of ordinary skill in the art would not consider a sequence of 10 nucleotides as identical to, for example, SEQ ID NO: 11, or its complement, both of which are 392 bases in length. Such an interpretation would be unreasonable. Therefore, the Applicants respectfully submit that Fodor does not anticipate any of the sequences claimed in claims 1 to 8 and respectfully request reconsideration and withdrawal of this rejection.

Claims 1 to 8 were also rejected under 35 U.S.C. § 102(b) as allegedly "being anticipated by Brennan (US Patent 5,474,796)." *Id.* The Applicants respectfully traverse this rejection.

As indicated above with respect to Fodor, one of ordinary skill in the art would not consider a short 3-mer as identical to, for example, SEQ ID NO: 11, or its complement, both of

which are 392 bases in length. Such an interpretation would be unreasonable and the Applicants respectfully submit that Brennan does not anticipate any of the sequences claimed in claims 1 to 8. Therefore, the Applicants respectfully request reconsideration and withdrawal of this rejection.

III. CONCLUSION

In view of the foregoing amendments and remarks, the Applicants respectfully submit that the present application is now in condition for allowance, and respectfully request notice of such. The Examiner is encouraged to contact the undersigned at 202-942-5746 if any additional information is necessary for allowance.

Respectfully submitted,

Date: November 3, 2006

Gautam Prakash, Ph.D. (Reg. Agent No. 53,481)
Thomas E. Holsten (Reg. Atty. No. 46,098)
David R. Marsh (Reg. Atty. No. 41,408)

Arnold & Porter LLP
555 Twelfth Street, N.W.
Attn: IP Docketing
Washington, DC 20004

Tel: 202-942-5000
Fax: 202-942-5999

Of Counsel:

Lawrence M. Lavin, Jr. (Reg. No. 30,768)
Thomas E. Kelley (Reg. No. 29,938)
Monsanto Company